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DEPARTMENT OF HEALTH & HUMAN SERVICES

1614

Public Health Service

Food and Drug Administration
Rockville MD 20857

OIPE JC67
MAY 10 1999
PATENT & TRADEMARK OFFICE

MAY - 5 1999

MAY 17 1999
MATRIX CUSTOMER SERVICE

Re: Lotemax™ and Alrex™
Docket No.: 98E-0789

MAY 14 1999

RECEIVED
JUN 03 1999
OFFICE OF PETITIONS
DEPUTY A/C PATENTS

60,034

The Honorable Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,996,335, filed by Nicholas S. Bodor, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Lotemax™ and Alrex™, the human drug product claimed by the patent.

The total length of the regulatory review period for Lotemax™ and Alrex™ is 3,092 days. Of this time, 2,017 days occurred during the testing phase and 1,075 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: September 22, 1989.

   The applicant claims January 2, 1989, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 22, 1989, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: March 31, 1995.

   The applicant claims March 29, 1995, as the date the new drug application (NDA) for Lotemax™ and Alrex™ (NDA 20-583) was initially submitted. However, FDA records indicate that NDA 20-583 was submitted on March 31, 1995.

3. The date the application was approved: March 9, 1998.

   FDA has verified the applicant's claim that NDA 20-583 was approved on March 9, 1998.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: Norman H. Stepno, Esq.
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